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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,106	04/19/2004	Gopi M. Venkatesh	EURA-008/00US 307853-2228	1448

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COOLEY GODWARD KRONISH LLP
ATTN: Patent Group
Suite 1100
777 - 6th Street, NW
WASHINGTON, DC 20001

EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
01/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/827,106	VENKATESH ET AL.	
	Examiner	Art Unit	
	Jagadishwar R. Samala	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claims Disposition

2. Claims 1-24 are pending and presented for examination.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al. (US 2005/0053655 A1) in view of Ohta, Motohiro et al. (EP 914818 A1).

Yang discloses a fast-disintegrating tablet (RDT) and method of preparing the (RDT) for pharmaceutical use. And the RDT contains microcapsules which contains an active pharmaceutical ingredient surrounded by a polymeric matrix formed by a hydrogel. And the microcapsules are about 50 microns in diameter and have a rapid disintegrating time of about 3 seconds to 3 minutes and are further separated from each other by a surfactant, before compressed into a tablet (see 0001 and 0069). And the active pharmaceutical ingredient in the RDT includes antiacid or anti-ulcer agents (such as cimetidine, ranitidine, nizatidine, roxatidine or famotidine); anti-inflammatory agents and the like (0018). And further the RDT contains an excipient such mannitol, lactose, sorbitol polyethylene glycol, crospovidone, flavors, and/or effervescent salts (0021 and 0053).

Yang meets the claim limitations as described above, but fails to teach explicitly separately granulating a sugar alcohol or a saccharide or a mixture thereof having an average particle size less than about 30 micorons therein. However, the use of sugar alcohol or saccharide, such as D-mannitol or lactose having an average particle diameter of not more than 30 microns as an ingredient and a disintegrant to make a tablet is well known in the art as show by Ohta.

Ohta discloses a method of preparing a rapidly disintegrating tablet comprising sugar alcohol or saccharide having an average particle diameter of not more than 30 microns, an active ingredient, and a disintegrant (see 0004).The tablet can be obtained by compressing and tableting after granulating a mixed powdered component comprising sugar alcohol or saccharide ground by means of a hammer mill or a jet mill

or the like (see 0018). The disintegrant mainly used such as crospovindone, crosscarmellose sodium, low substituted hydroxypropylcellulose or the like which is widely used for drugs and food (see 0016). Also sugar alcohol used were D-mannitol, sorbitol, and saccharide or like which is widely used for drugs and foods. The amount of sugar alcohol or saccharide is preferably about 60-95 % by weight of tablet (see 006 and 0019).The amount of taste masked active ingredient is 0.01-30 %, and the amount of disintegrant present is preferably about 1-30mg per dosage, and more preferably 1-10 % per one tablet (see 0021).

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate sugar alcohol or saccharide, such as D-mannitol or lactose having an average particle diameter of not more than 30 microns into the tablets as taught by Yang. In view of Ohta, motivation would come from the rapidly disintegrable tablet comprising active ingredient and sugar alcohol or saccharide which does not require a special pharmaceutical manufacturing technology and can be simply and easily produced by normal equipment.

When these references are taken together, one would have been motivated to extend Ohta's teaching to add sugar alcohol or saccharide having an average particle diameter of not more than 30 microns to maximize therapeutic efficacy. As suggested by cited references, one would have reasonably expected successful addition of sugar alcohol or saccharide (such as D-mannitol or sorbitol) because the effectiveness, extra benefits (i.e., a method for preparing taste masked fast disintegrating tablets) and safety are already well proven and are well suggested by latter reference cited.

One would have been motivated to do so, with reasonable expectation of success because it is always desirable to have extended therapeutic modalities to improve patient's compliance by enhancing patient satisfaction and increasing the selection option. The techniques and skills required for making such substitution is conventional knowledge or well within the skills of ordinary artisan as evidenced by these references cited.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01 (a).

Conclusion

1. No claims are allowed at this time.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jagadishwar R Samala
Examiner
Art Unit 1618

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MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER